



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service **JEP**
91055d
Food and Drug Administration
New Orleans District Office
6600 Plaza Drive, Suite 400
New Orleans, LA 70127

March 26, 2001

VIA FEDERAL EXPRESS

FACILITY ID# 140525

Nancy Lewis, Administrator
St. Vincent's Hospital Comprehensive Breast Center
810 St. Vincent's Drive
Birmingham, AL 35205

Warning Letter No. 01-NSV-20

Dear Ms. Lewis:

Your facility was inspected on March 15, 2001, by a representative of the State of Alabama on contract to the Food and Drug Administration (FDA). This inspection revealed that your facility failed to comply with the Quality Standards for Mammography (Standards) as specified in Title 21, Code of Federal Regulations (CFR), Part 900.12, as follows:

Level 2 (Repeat)

Corrective action was not documented before further exams for the density difference of the phantom image that fell outside the allowable regulatory limits for unit 1, [REDACTED], room Two.

This specific deficiency appeared on the Post Inspection Report, which was sent to your facility by the state inspector along with instructions on how to respond to this finding.

Your failure to take appropriate corrective actions before further exams was also cited during our inspection on March 9, 2000. Specifically, Corrective action for a failing image score (before further exams) was not documented for unit 1, [REDACTED], room TWO. A response from your facility dated May 16, 2000 indicated that the deficiency had been corrected

It is your responsibility to ensure adherence to each requirement of the Mammography Quality Standards Act of 1992 (MQSA) and FDA's regulations. You are responsible for investigating and determining the cause of this deficiency as identified and to promptly initiate permanent corrective action.

If you fail to properly address this deficiency, FDA may, without further notice, initiate regulatory action. Under MQSA, FDA may:

- impose civil money penalties on a facility of up to \$10,000 for each failure to substantially comply with, or each day of failure to comply with the Standards.

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- suspend or revoke a facility's FDA certificate for failure to comply with the Standards
- seek an injunction in federal court to prohibit any mammography activity that constitutes a serious risk to human health.

Within 15 working days after receiving this letter, you should notify FDA in writing of each step your facility is taking to prevent the recurrence of any similar violation.

If your facility is unable to complete this corrective action within 15 working days, you should state the reason for the delay and the time within which the corrections will be completed.

Your reply should be directed to Joseph E. Hayes, Compliance Officer, Food and Drug Administration, 297 Plus Park Boulevard, Nashville, Tennessee 37217, telephone 615/781-5389, extension 125, with a copy to the State of Alabama. Should you have questions regarding this letter or MQSA standards, you may call Karen Smallwood, Radiation Specialist, at 615/781-5380, extension 144.

Sincerely,



Carl E. Draper
Director, New Orleans District

CED:KRS:man

cc: State of Alabama
Dept. of Public Health
Office of Radiation Control
P.O. Box 303017
Montgomery, AL 36130-3017
ATTN: Richard Glass

Priscilla F. Butler, MS
Director, Breast Imaging Accreditation Programs
Standards and Accreditation Department
American College of Radiology
1891 Preston White Drive
Reston, Virginia 20191

Director
Government Relations
C/o American College of Radiology
1891 Preston White Drive
Reston, VA 22091